105 CMR: Department of Public Health

105 CMR 660.000 Cigarette and Smokeless Tobacco Products: Reports of Added Constituents and Nicotine Ratings

660.001: Purpose

The purpose of these regulations is to implement M.G.L. Chapter 94, section 307B, which mandates reporting of certain information relating to tobacco products to the Department of Public Health.

660.002: Authority

These regulations are adopted pursuant to M.G.L. c.94, s. 307B.

660.003: Definitions

As used in 105 CMR 660.000, et seq., the following terms shall have the following meanings, unless the context clearly requires otherwise:

Added Constituent means any ingredient, substance, chemical or compound other than tobacco, water or reconstituted tobacco sheet, which is added by the manufacturer to the tobacco, paper or filter of a cigarette or the tobacco of a smokeless tobacco product during the processing, manufacture, or packing of the cigarette or smokeless tobacco product.

Annual Report means a tobacco manufacturer's annual report to the Department, which provides, for each brand of cigarette and smokeless tobacco product, added constituent information and nicotine yield ratings, as described in 105 CMR 660.100 to 660.103.

Attorney General means the Attorney General of the Commonwealth of Massachusetts.

Cigarette means any product (including components, accessories, or parts) which contains or delivers nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(A) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(B) Any roll of tobacco wrapped in a tendu or temburni leaf, commonly referred to as 'bidis'; or

(C) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filter, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette.

Commissioner means the Commissioner of the Department of Public Health.

Could Reduce Risks to the Public Health means that knowledge about an added constituent could result in reduced risk of adverse health effects associated with tobacco use, including but not limited to nicotine addiction and adverse health effects associated with exposure to environmental tobacco smoke.

Department means the Department of Public Health.

Federal Trade Commission means the United States Federal Trade Commission.

Manufacturer means any person or entity, including any repacker or relabeler, manufacturing, fabricating, assembling, processing, or labeling a finished cigarette or smokeless tobacco product. The term does not include any person or entity only distributing finished cigarettes or smokeless tobacco products.

Smokeless Tobacco means any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity without burning.

660.100: General Requirements for Annual Reports by Manufacturers

(A) On December 15, 1997, and on every December 1 thereafter, the manufacturer of any cigarette or smokeless tobacco product sold in the Commonwealth as of that date shall report to the Department, in accordance with these regulations, the added constituents and nicotine yield rating requirements of each such cigarette or smokeless tobacco product. To the maximum extent possible, such report shall be submitted electronically to the Department, in accordance with the technical specifications of the Departments. All raw data generated by testing in accordance with these regulations should be submitted as part of this report.

(B) Nothing in this section shall prohibit a manufacturer or distributor of cigarettes or smokeless tobacco products from selling such products to an in-state merchant for sale or distribution outside of the Commonwealth.

660.101: Added Constituent Reporting Requirements

In each annual report, a manufacturer shall provide the following information for each brand, sub-brand and generic unbranded cigarette or smokeless tobacco product sold in the Commonwealth:

(A) the identity of all added constituents in the cigarette or smokeless tobacco product listed in descending order by weight, numerical count or measure; provided, however, that in the manufacturer's discretion, the identity of added constituents which occur at levels below one part per million (0.0001%), by weight of the tobacco and added constituents, may be provided as a separate listing, with the added constituents reported in alphabetical order, rather than in descending order by weight, numerical count or measure. Each added constituent shall be reported by its chemical name and chemical abstract service (CAS) registry number, if available. See 105 CMR 660.400 for the added constituent reporting form;

(B) the name, job title, address, and telephone number of the individual designated by the manufacturer as the Department's contact person concerning 105 CMR 660.000.

660.102: Cigarette Nicotine Yield Rating Reporting Requirements: General

(A) In each annual report submitted pursuant to 660.100, a manufacturer shall include, as part of the nicotine yield rating for each brand, sub-brand and generic unbranded cigarette, the information specified in sections 660.102.

(B) For each brand of cigarette sold in the Commonwealth, manufacturers shall provide to the Department by December 1, 2000, and by every December 1 thereafter, the following information about the product and its design characteristics that affect nicotine yield:

(1) U.S. market share (%), most recent available
(2) Menthol/non-menthol
(3) Cigarette length, mm
(4) Cigarette circumference, mm
(5) Packaging (e.g. hard pack, soft pack)
(6) Regular/generic price tier
(7) Type of filter (e.g. cellulose acetate)
(8) FTC nicotine, most recent available
(9) FTC tar, most recent available
(10) FTC carbon monoxide(CO), most recent available
(11) FTC puff count, most recent available
(12) Weight of tobacco, g
(13) Tobacco blend density
(14) Nicotine content, mg/g (see 660.500 (B)(1))
(15) Nicotine content, mg/cig (see 660.500 (B)(1))
(16) Moisture (percent) (see 660.500 (B)(1))
(17) Percent filter ventilation (see 660.500 (B)(2))

(18) Paper porosity (see 660.500 (B)(3))
(19) Pressure drop (see 660.500 (B)(4))
(20) Resistance to draw (see 660.500 (B)(4))

(C) For each brand of cigarette not selected for testing and reporting pursuant to section 660.103, the manufacturer shall provide to the Department a nicotine yield rating determined through use of a multiplier approved by the Department that approximates the nicotine yield for the product under average smoking conditions.

(D) FTC nicotine, tar, and carbon monoxide ratings shall be obtained from the most recent Federal Trade Commission report entitled "*Tar, Nicotine, and Carbon Monoxide of the Smoke of Varieties of Domestic Cigarettes.*" If no report has been made to the Federal Trade Commission, the manufacturer shall report the nicotine, tar, and carbon monoxide levels determined in accordance with the FTC testing methods specified in section 660.500(C).

(E) Cigarette design characteristics shall be determined in accordance with the methods specified in subsections 660.500 (B).

660.103: Cigarette Nicotine Yield Reporting Requirements: Selected Brands

(A) The Department will select by March 1, 2001 and by every March 1 thereafter, a sample set of 75 brands for testing in accordance with the requirements of subsection 660.103(A). Manufacturers will be notified promptly of the selections made by the Department. For each of the 75 brands selected by the Department, the annual report submitted pursuant to 660.100 shall include nicotine delivery under average smoking conditions, reported in milligrams of nicotine per cigarette.

(1) Manufacturers shall use the Federal Trade Commission testing method, as described and modified in section 105 CMR 660.500(C), with the puff volume adjusted to 45 milliliters, puff interval adjusted to 30 seconds, and puff duration to 2 seconds. The average number of puffs per cigarette taken in this condition shall be reported. Cigarettes with ventilation holes must have the holes half blocked during testing (see 660.500 (C)(2) for hole blocking method).

(2) Testing and measurement for nicotine yield shall comply with the sampling and conditioning standards set forth in 105 CMR 660.500 (A). The cigarette nicotine yield shall be reported to the Department on the form attached to these regulations as 105 CMR 660.600.

(B) The Department will select for additional testing by March 1, 2002, and by every March 1 thereafter, a subset of 15 brands from the sample of 75 brands selected for testing in accordance with section 660.103(A). Manufacturers will be notified promptly of the selections made by the Department. For each of the 15 selected brands, the annual report submitted pursuant to 660.100 shall include the following information related to nicotine yield:

(1) pH of cigarette smoke, as determined in accordance with the method specified in 105 CMR 660.500(D) or comparable method approved by the Department;

(2) human smoking parameters, that is smoking behaviors that may affect the smoker's intake of nicotine, as determined in accordance with the method specified in 105 CMR 660.500 (E) or comparable method approved by the Department; and

(3) human nicotine intake, as determined in accordance with the method specified in 105 CMR 660.500 (F) or comparable method approved by the Department.

660.110: Smokeless Tobacco Products: Nicotine Yield Reporting Requirements

Smokeless tobacco product manufacturers shall include in their annual report the nicotine yield for each brand, sub-brand or generic unbranded smokeless tobacco product sold in the Commonwealth, which shall include:

(A) pH of tobacco;
(B) moisture content as a percent of weight of tobacco;
(C) nicotine in milligrams per gram of tobacco;
(D) nicotine as a percent of dry weight of tobacco;
(E) percent of unionized (free) nicotine; and
(F) total unionized (free) nicotine in milligrams per gram of tobacco

The smokeless tobacco nicotine yield shall be reported to the Department as specified on the form attached to these regulations as 105 CMR 600.600.

660.200: Determining Public Availability of Added Constituent Information in Annual Report

(A) After receipt of an annual report filed pursuant to section 660.101, the Department shall make a written preliminary determination as to whether there is a reasonable scientific basis for concluding that the public availability of some or all of the added constituent information contained in the report could reduce risks to public health. The determination shall include the Department's reason(s) for proposing to make the information available.

(B) If the Department preliminarily determines that making available the information about some or all of the added constituents is warranted under M.G.L. c. 94, § 307B and these regulations, the Department shall so notify the manufacturer of each added constituent proposed to be made available and shall provide the manufacturer its written preliminary determination. The manufacturer shall have sixty (60) days after its receipt of the written preliminary determination to provide written comment to the Department on the preliminary determination.

(C) Following expiration of the sixty (60) day response period specified in section 660.200 (B), the Department shall make a final written determination, including the reasons for so deciding, if it finds that there is a reasonable scientific basis for concluding that

making available to the public information about some or all of the added constituents could reduce risks to the public health.

(D) In the event the Department makes the determination referred to in subsection 660.200(C), it shall request the advice of the Attorney General as to whether making available this information to the public would constitute an unconstitutional taking of property. Information submitted to the Department pursuant to sections 660.101 and 660.200 (B) shall be regarded by the Department as confidential, and shall not be made available to the public, during the period in which the Department is awaiting advice from Attorney General pursuant to this subsection.

(E) In the event that the Attorney General advises the Department that making available to the public information about some or all of the added constituents referred by the Department pursuant to section 660.200(D) would not constitute an unconstitutional taking, the Department shall give the manufacturer sixty (60) days written notice of the information to be made available. At the end of the sixty day period, the Department shall make such information available to the public for inspection and copying.

(F) (1) Within thirty days of issuance by the Department of a written notice pursuant to 105 CMR 660.200(E), the manufacturer of any brand, sub-brand or generic unbranded cigarette or smokeless tobacco product containing one or more added constituent(s) identified in said notice (hereafter an "affected product") may notify the Department in writing that it will, within a period of 90 days of receipt of the said notice from the Department, cease sales in Massachusetts of certain affected product(s) or remove certain affected product(s) from the Massachusetts market in order to reformulate the product(s) to remove the added constituent(s) identified in the notice issued pursuant to 105 CMR 660.200(E). For products as to which a manufacturer submits timely written notice to the Department under this subsection 660.200(F)(1), the Department shall continue to treat as confidential (and shall not release to the public) for the duration of the 90 day period the added constituent information that had been identified for public release under 105 CMR 660.200(E).

(2) If a manufacturer, within the 90 day period, ceases sales of the affected product(s) or removes the affected product(s) from the Massachusetts market in accordance with its notice to the Department, the Department shall make a determination that there is no reasonable scientific basis for concluding that public availability of the added constituent information contained in the report(s) about the affected product(s) could reduce risks to the public health. The Department thereafter shall treat as confidential (and shall not release to the public) any added constituent information previously submitted by the manufacturer pursuant to 105 CMR 660.101 for such affected product(s). If a manufacturer does not cease sales of the affected product(s) or remove the affected product(s) from the Massachusetts market in accordance with its notice to the Department within the additional 90 day period, the Department shall at the end of the 90 day period make available to the public the information identified in the Department's notice pursuant to subsection 660.200(E).

(3) If a manufacturer intends to resume sales in Massachusetts of an affected product after it has been reformulated, the manufacturer shall file with the Department, prior to resumption of sales, a certification that the reformulated product does not contain any of the added constituent(s) identified in the notice issued pursuant to subsection 660.200(E) that preceded the product reformulation. The manufacturer shall also file all annual reports thereafter required under M.G.L. c. 94, s. 307B and 105 CMR 660.000 for such product.

(G) The Department shall treat information submitted pursuant to 105 CMR 660.101 as confidential unless and until:

(1) a manufacturer notifies the Department in writing that it does not consider information it has submitted in its annual report concerning added constituents to be confidential;

(2) a determination to release the information is made in accordance with 105 CMR 660.200(A) through (E), the sixty day period referred to in 105 CMR 660.200(E) has elapsed, and no complaint has been filed in a court of competent jurisdiction challenging disclosure of the information on the grounds that disclosure would make available to the public a trade secret;

(3) the disclosure of the information is authorized by judicial decision and the time for appeal in a court of competent jurisdiction has passed; or

(4) the disclosure of the information is authorized by agreement of the parties, as specified in section 660.200(H).

If a manufacturer submits in timely fashion to the Department written notice in accordance with 105 CMR 660.200(F)(1), the Department shall treat information submitted by that manufacturer pursuant to 105 CMR 660.101 as confidential as and to the extent provided in 105 CMR 600.200(F).

(H) In the event that a manufacturer files a complaint in a court of competent jurisdiction within the sixty day notice period specified in section 660.200(E), challenging a proposed disclosure of information by the Department on the grounds that disclosure would make available to the public a trade secret, the Department shall not disclose any of the information in question unless and until:

(a) the parties agree in writing to disclosure; or

(b) the court renders a decision authorizing disclosure; and

(c) the time has passed for filing an appeal of the decision in a court of competent jurisdiction.

(I) A manufacturer submitting written comments to the Department pursuant to Section 660.200(B) may request that its submission, and any preliminary or final determinations by

the Department pursuant to this section, be treated as confidential. The Department will thereafter treat such submission(s) and determinations as confidential to the extent permitted by law; provided, however, that upon making information available to the public pursuant to subsection 660.200 (F), the Department shall no longer treat as confidential the preliminary and final determinations it rendered, or any written comments submitted by a manufacturer.

(J) The Commissioner shall establish written procedures to maintain the confidentiality of information treated as confidential pursuant to section 660.200 (F), (G) and (H). Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent shall:

(1) take physical possession of the information and, when not in use by a person authorized by the Commissioner to have access to such information, store it in a locked cabinet or file; and

(2) maintain a list of persons authorized by the Commissioner to have access to such records and a daily log of each person who inspects the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to make available the information to anyone who is not entitled to have access to the information, and informed of the penalties for failing to comply.

660.300: Severability

If any provisions of 105 CMR 660.000 are held invalid for any reason whatsoever, such declaration shall not effect any other portion of 105 CMR 660.000, which shall remain in full force and effect, and to this end, the provisions of 105 CMR 660.000 et seq. are hereby declared severable.

660.400: Added Constituent Reporting Form

Brand Name _____ **Sub Brand** _____

Please list added constituents in descending order according to weight, measure or numerical count.

	Chemical Name	C.A.S. Number
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		

660.500: Testing Methods

(A) Sampling and Conditioning. Conditioning for testing of tobacco products shall be in accordance with the International Organization for Standardization (ISO), 3402, third edition, 1991-07-01 entitled *Tobacco and Tobacco Products -- Atmosphere for Conditioning and Testing*, or comparable method approved by the Department. Cigarettes shall be sampled using international standard ISO 243:98 (E) entitled *Cigarette – Sampling*, or comparable method approved by the Department. Manufacturers will sample 20 packages for each tested brand at the point of production, drawing up to three cigarettes per package for a total sample of 60 cigarettes per brand for nicotine testing. Smokeless tobacco products will follow the sampling protocol outlined in the Requirements for Annual Submission of the Quantity of Nicotine Contained in Smokeless Tobacco Products Manufactured, Imported, or Packaged in the United States, most recently published in the Federal Register on March 23, 1999 (Volume 64, Number 55), or comparable method approved by the Department.

(B) Product Design Characteristics.

(1) Nicotine content and moisture content in cigarette and smokeless tobacco products and pH in smokeless tobacco products shall be measured in accordance with the guidelines published in the Requirements for Annual Submission of the Quantity of Nicotine Contained in Smokeless Tobacco Products Manufactured, Imported, or Packaged in the United States, most recently published in the Federal Register on March 23, 1999 (Volume 64, Number 55), or comparable method approved by the Department.

(2) Percent filter ventilation means the level of air dilution in the whole smoke, as provided by the perforations made in the cigarette filter tip, described in percent. This shall be measured in accordance with ISO standard 9512, or comparable method approved by the Department

(3) Paper porosity shall be determined based on the CORESTA standard (where a CORESTA unit is the flow of air in cm^3 per minute passing through a 1 cm^2 surface of a test apparatus at a measuring pressure of 1.00 kPA) or comparable standard approved by the Department.

(4) Pressure drop of filter rods and draw resistance will be determined in accordance with ISO 6565: 1999 or comparable method approved by the Department.

(C) Modified FTC Testing Method.

(1) Nicotine delivery under average smoking conditions shall be evaluated using the Cambridge Method, which has been approved by the Federal Trade Commission (FTC) as the standard for nicotine testing since 1966, and adopted for international purposes by the ISO. See Federal Register, Vol. 32, No.147, page 11178, dated

August 1, 1967, as modified by the FTC in Federal Register, Vol. 45 No. 134, pages 46483-46487, dated July 10, 1980; ISO 10315, 91-08-01 entitled "Cigarettes-Determination of Nicotine in Smoke Condensates-Gas-Chromatographic Method"; ISO 3308, third edition, 1991-10-15, "Routine Analytical Cigarette-Smoking Machine - Definition of Standard Conditions"; and ISO 7201, second edition, 1997-01-15, "Routine Analytical Smoking Machine Additional Test Methods". Three cigarettes shall be randomly selected from each pack for a sample of 60 cigarettes per brand.

(2) The Department has modified the FTC and ISO conditions to require the following changes to the testing method:

(a) Puff volume as prescribed in the FTC method and in the ISO 3308: 4.3 shall be increased from 35 ml to 45 ml;
(b) Puff frequency as prescribed in the FTC method and ISO 3308: 4.4 shall be changed from one puff each minute to one puff every 30 seconds;
(c) Puff duration shall remain at two seconds;
(d) 50% of the ventilation holes must be blocked by placing a strip of mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape (Acetate) or other method approved by the Department. The tape shall be cut so that it covers 50% of the circumference and is tightly secured from the end of the filter to the tipping overwrap seam;
(e) Number of cigarettes smoked per port shall be three, provided that the limit of 150 milligrams of tar is not exceeded (ISO 4387).

(D) pH Testing Method. Testing for pH shall be conducted on a puff by puff basis, in accordance with the testing method described in Sensabough, A. J., Jr. and Candiff, R.H., "A New Technique for Determining the pH of Whole Tobacco Smoke", Toh.Sci., 11: 25-30 (1967) and Brunnemann, K.D. and Hoffman, D., "The pH of Tobacco Smoke", Food, Cosmet. Toxicol., 112:115 (1974), or comparable method approved by the Department.

(E) Human Smoking Parameters. Sixty smokers (30 male, 30 female) shall be selected for testing of each brand pursuant to section 660.103(B) (for a total of 900 smokers). They shall have smoked for at least five years, currently smoke at least 15 cigarettes per day and have smoked the brand to be tested, or a brand with equivalent levels of tar and nicotine, for at least three months immediately prior to testing. Smoking behavior will be measured using the method described in MV Djordjevic, J Fan, S Ferguson, and D Hoffmann, "Self-regulation of Smoking Intensity: Smoke Yields of the Low-nicotine, Low-'tar' Cigarettes," *Carcinogenesis* 1995; 16:2015-2021, or comparable method approved by the Department. Reporting for each brand will include the following data (including where applicable, the standard variation of the mean, 95% confidence limit and coefficient of variation):

1) average puff volume
2) average puff duration

3) average interval between puffs
4) average pressure to draw puffs
5) average number of puffs
6) average butt length
7) smoker history: daily average cigarettes, years smoked, age of initiation

Patterns of filter blocking shall also be recorded for each brand. Filters will be evaluated after smoking according to a 3-level scale (no blockage, incomplete blockage, total blockage) as measured in LT Kozlowksi, JL Pillitteri, and CT Sweeney, "Misuse of 'Light' Cigarettes by Means of Vent Blocking," *Journal of Substance Abuse* 1994; 6:333-336, or comparable method approved by the Department.

(F) Human Nicotine Intake. The same set of sixty smokers identified in 660.500 (E) shall be tested for nicotine intake for each brand (900 total) by collecting a 24-hour urinary excretion sample and testing for levels of nicotine and its metabolite, cotinine, using gas chromotography-mass spectrometry, as described in Jacob P 3rd, Benowitz NL, Shulgin AT, "Recent Studies of Nicotine Metabolism in Humans," *Pharmacology and Biochemical Behavior* 1988; 30(1):249-53, or comparable method approved by the Department. Research on human intake of nicotine shall be conducted in accordance with federal regulations governing protection of human subjects, Title 45 of the Code of Federal Regulations, Part 46.

660.600: Cigarette Nicotine Yield Rating Form

Brand _____ Sub-Brand _____

U.S. market share (%) _____ Menthol/non-menthol _____
Cigarette length, mm _____ Cigarette circumference, mm _____
Packaging _____ Regular/generic price tier _____
Type of filter _____ FTC nicotine _____
FTC tar _____ FTC carbon monoxide(CO) _____
FTC puff count _____ Weight of tobacco, g _____
Tobacco blend density _____ Nicotine content, mg/g _____
Nicotine content, mg/cig _____ Moisture (%) _____
Percent filter ventilation _____ Paper porosity _____
Pressure drop _____ Resistance to draw _____

Nicotine delivery under average smoking conditions _____
Multiplier if used _____

(Additional information for selected brands)

pH _____

Puff	1	2	3	4	5	6	7	8	9	10	11	12	13	Mean

Average puff volume _____ Average puff duration _____
Average puff interval _____ Average pressure to draw _____
Average puff count _____ Average butt length (mm) _____
Pattern of filter blocking (# smokers):
None _____ Incomplete _____ Total _____

Nicotine intake (ug/L) _____ Std Dev _____ C.V. _____
Cotinine intake (ng/L) _____ Std Dev _____ C.V. _____

Smokeless Tobacco Nicotine Yield Rating Form

Brand _____ Sub-Brand _____

Moisture Content in Percent _____
Nicotine as a Percent of Dry Weight Tobacco _____
Nicotine in Milligrams per Gram of Tobacco _____
pH _____
Total Unionized (free) Nicotine _____